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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/654,743	09/01/2000	Robert G. Korneluk	07891/003005	7148
21559	7590	03/25/2004	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			KAUSHAL, SUMESH	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/654,743

Applicant(s)

KORNELUK ET AL.

Examiner

Sumesh Kaushal Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50 and 79-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50 and 79-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Applicant's response filed on 01/19/04 has been acknowledged.

Claims 1-49 and 51-78 are canceled.

Claims 79-89 are newly filed.

Claim 50 is amended.

Claims 50 and, 79-89 are pending and are examined in this office action.

*Applicants are required to follow Amendment Practice under revised **37 CFR §1.121**. The fax phone numbers for the organization where this application or proceeding is assigned is **703-872-9306**.*

Double Patenting

1. Claim 50 stand rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 7 of prior U.S. Patent No. 6156535. This is a double patenting rejection.

Claim 7 of the U.S. Patent No. 6156535 claims "A substantially pure nucleic acid encoding a baculovirus inhibitor of apoptosis repeat (BIR) domain, said nucleic acid comprising a sequence selected from the group consisting of SEQ ID NO: 45, SEQ ID NO: 46, **SEQ ID NO: 47**, SEQ ID NO: 49, SEQ ID NO: 50, **SEQ ID NO: 51**, SEQ ID NO: 53, SEQ ID NO: 54, SEQ ID NO: 55, SEQ ID NO: 57, SEQ ID NO: 58, SEQ ID NO: 59, SEQ ID NO: 61, SEQ ID NO: 62, SEQ ID NO: 63, SEQ ID NO: 65, SEQ ID NO: 66, and SEQ ID NO: 67" the subject matter of which is identical to the subject matter of claim 50 of instant application which recites "A *substantially pure nucleic acid, said nucleic acid comprising a sequence selected from the group consisting of SEQ ID NO: 47 and SEQ ID NO: 51*". Even though the applicant has amended claim 50, the invention as claimed after the amendment is "same invention", since the SEQ ID NO:47 and 51 of instant application matches 100% to the SEQ ID NO:47 and 51 of US 6156535.

Under the law a rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Double Patenting (OPD)

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 79-84 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,156,535 in view of Ausubel et al (Short Protocols in Molecular Biology, 3rd Edition, Wiley & Sons Inc. 1992, see pages 9.1, 16.3-5 and 16.58-62).

Claims 79-84 are drawn to a vector and host cells comprising the nucleic acid sequence of SEQ ID NO: 47 and 51.

The U.S. Patent No. 6156535 claims (see Claim 7) "A substantially pure nucleic acid encoding a baculovirus inhibitor of apoptosis repeat (BIR) domain, said nucleic acid comprising a sequence selected from the group consisting of SEQ ID NO: 45, SEQ ID NO: 46, **SEQ ID NO: 47**, SEQ ID NO: 49, SEQ ID NO: 50, **SEQ ID NO: 51**, SEQ ID NO: 53, SEQ ID NO: 54, SEQ ID NO: 55, SEQ ID NO: 57, SEQ ID NO: 58, SEQ ID NO: 59, SEQ ID NO: 61, SEQ ID NO: 62, SEQ ID NO: 63, SEQ ID NO: 65, SEQ ID NO: 66, and SEQ ID NO: 67" the subject matter of which is identical to the subject matter of claim 50 of instant application which recites "*A substantially pure nucleic acid, said nucleic acid comprising a sequence selected from the group consisting of SEQ ID NO: 47 and SEQ ID NO: 51*".

However US Patent No. 6156535 does not claim an expression vector and host cells comprising the nucleic acid sequences of SEQ ID NO:47 and 51.

Ausubel teaches a method for transforming prokaryotic and eukaryotic host cells with plasmid and viral expression vectors to produce or express the protein of interest (pages 16.3-5 and 16.58-62).

Thus, it would have been obvious to one ordinary skill in the art at the time of filing to construct an expression vector comprising the nucleotide sequences of SEQ ID NO:47 and 51. It would have been further obvious to make recombinant prokaryotic and eukaryotic cells host cells by transfecting the expression vector. One would have been motivated to do so in order to make recombinant proteins. One would have a reasonable expectation of success because cloning and gene expression in prokaryotic and eukaryotic has been routine in the art at the time of filing. Thus the invention as claimed is prima facie obvious in view of cited art of record.

4. Claim 85 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,156,535. Although the conflicting claims are not identical, they are not patentably distinct from each other because the nucleic acid sequences of SEQ ID NO:47 and 51 of US '535 would inherently encode the amino acid sequence of SEQ ID NO: 24 and 25 of instant application. Therefore the nucleic acid sequences which encode the amino acid sequences of SEQ ID NO:24 and 25 are obvious in view of US '535.

5. Claims 86-89 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,156,535 in view of Ausubel et al (Short Protocols in Molecular Biology, 3rd Edition, Wiley & Sons Inc. 1992, see pages 9.1, 16.3-5 and 16.58-62).

Claims 86-87 are drawn to a vector comprising the nucleic acid sequences encoding the amino acid sequences of SEQ ID NO: 24 and 25. Claims 88-89 are drawn to a cell expressing the nucleic acid sequences encoding the amino acid sequences of SEQ ID NO: 24 and 25.

The U.S. Patent No. 6156535 claims (see Claim 7) "A substantially pure nucleic acid encoding a baculovirus inhibitor of apoptosis repeat (BIR) domain, said nucleic acid comprising a sequence selected from the group consisting of SEQ ID NO: 45, SEQ ID NO: 46, **SEQ ID NO: 47**, SEQ ID NO: 49, SEQ ID NO: 50, **SEQ ID NO: 51**, SEQ ID NO: 53, SEQ ID NO: 54, SEQ ID NO: 55, SEQ ID NO: 57, SEQ ID NO: 58, SEQ ID NO: 59, SEQ ID NO: 61, SEQ ID NO: 62, SEQ ID NO: 63, SEQ ID NO: 65, SEQ ID NO: 66, and SEQ ID NO: 67". The nucleic acid sequences of SEQ ID NO:47 and 51 of US '535 would inherently encode the amino acid sequence of SEQ ID NO: 24 and 25 of instant application.

However US Patent No. 6156535 does not claim an expression vector and host cells comprising the nucleic acid sequences which encode the amino acid sequences of SEQ ID NO:24 and 25.

Ausubel teaches a method for transforming prokaryotic and eukaryotic host cells with plasmid and viral expression vectors to produce or express the protein of interest (pages 16.3-5 and 16.58-62).

Thus, it would have been obvious to one ordinary skill in the art at the time of filing to construct an expression vector comprising the nucleotide sequences of SEQ ID NO:47 and 51. It would have been further obvious to make recombinant prokaryotic and eukaryotic cells host cells by transfecting the expression vector. One would have been motivated to do so in order to make recombinant proteins. One would have a reasonable expectation of success because cloning and gene expression in prokaryotic and eukaryotic has been routine in the art at the time of filing. Thus the invention as claimed is prima facie obvious in view of cited art of record.

Claim Rejections - 35 USC § 112

6. In response to the amendment of claim 50 the rejection under 35 USC112(1) regarding Written description and Enablement has been withdrawn.

7. Claims 81-83 and 88-89 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated cell expressing the SEQ ID NO:47 or 51 which encodes the amino acid sequences of SEQ ID NO:24 or 25 respectively, does not reasonably provide enablement for any and all types of cell in-vivo, wherein the cells are transduced via method of gene therapy or via making a transgenic animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of the invention instant as claimed encompass a cell in-vivo, which contains the claimed nucleic acid sequences. Therefore, the invention reads upon a cell obtained by a method of gene therapy or a cell present in a transgenic animal. The

art at the time of filing clearly teaches that the gene therapy is considered highly experimental area of research at this time, and both researchers and the public agree that demonstrable progress to date has fallen short of initial expectations (Rosenberg et al, Science 287:1751, 2000). Similarly, the state of transgenic art at the time of filing was such that phenotype of an animal is determined by a complex interaction of genetics and environment. (Wood. Comp. Med. 50(1): 12-15, 2000, see page12). Therefore, considering the unpredictability in the art and the limited amount of guidance provided in the instant specification, it would require an undue amount of experimentation to exercise the invention as claimed. In instant case making a host cell to produce recombinant protein (in-vivo), wherein the host cells is created by method of gene therapy or transgenic art are not considered routine in the art and without sufficient guidance the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). Claims drawn to an isolated host cell would obviate this rejection.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 84 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 84 recites the limitation "The Cell" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Conclusion


No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 571-272-0781.

The fax phone number for the organization where this application or proceeding is assigned is **703-872-9306**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


GERRY LEFFERS
PRIMARY EXAMINER

Sumesh Kaushal
Examiner Art Unit 1636